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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,264	03/23/2001	Andrey A. Boukharov	38-21(51237)G	8785

28381 7590 04/07/2003

ARNOLD & PORTER  
IP DOCKETING DEPARTMENT; RM 1126(b)  
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WASHINGTON, DC 20004-1206

EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631  
DATE MAILED: 04.07.2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/815,264

Applicant(s)

BOUKHAROV ET AL.

Examiner

Marjorie A. Moran

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 6,7 and 12-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-5 and 8-11, and of SEQ ID NO: 1 in Paper No. 8, filed 3/6/03 is acknowledged. The traversal is on the ground(s) that both Groups I and II are directed to nucleic acids comprising the same SEQ ID NO: and that it would not be an serious burden for the examiner to search and examine all Groups and/or to search and examine ten sequences.

This is not found persuasive because although the nucleic acids of Groups I and II may comprise the same sequence, they are not actually directed to the same nucleic acid sequences/structures. As set forth in the restriction requirement, the nucleic acids of Group II are limited to comprise sequences heterologous to those of Group I, and are therefore necessarily directed to a sequence/structure which is different from that of Group I. Different structures are considered different products, therefore the examiner maintains that restriction between Groups I and II is proper. While a search for Group I may overlap that of Group II, the searches are not the same (i.e. Group II requires a search for the heterologous limitations, and therefore requires a search of the prior art not required for Group I). With regard to a search for all Groups, or for more than one sequence, applicant is reminded that a search for any single Group and/or sequence requires a search of both nonpatent and patent literature, and a search of foreign patents as well as US patents, therefore the examiner maintains that search and examination of more than one Group and/or sequence would be a serious burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6-7, 12-17, 18-37, and all sequences other than SEQ ID NO: 1 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

An action on the merits of elected claims 1-5 and 8-11, as they read on elected SEQ ID NO: 1, follows.

#### ***Information Disclosure Statement***

The IDS filed 9/18/01 has been considered in full.

#### ***Specification***

The disclosure is objected to because of the following: Table 2, set forth on pages 91-93, is incomprehensible, apparently due to a formatting problem or error in printing the Table. Tables 4-6, disclosed on a CD-ROM in a file labeled pa\_00329.tst, and incorporated by reference on page 1 of the specification, are incomprehensible, also apparently due to formatting problems. The columns, and information therein, in Tables 2 and 4-6 are so scrambled that it is impossible to read the Tables. This objection may be overcome by re-formatting the Tables such that the columns, and information therein, are aligned and can be easily read in either paper form (Table 2) or electronic form (Tables 4-6). It is noted that the column headings and information in

Table 3, also presented on the CD-ROM, are not aligned. However, the information in Table 3 is not so scrambled as to be incomprehensible, just somewhat difficult to read. For clarity, the examiner recommends also re-formatting Table 3 to make the column heading and information therein easier to read. Appropriate correction is required.

Applicant is reminded that any amendment to a compact disc must comply with 37 CFR 1.52, specifically section (e) (4).

The disclosure is also objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See e.g. pages 78-86 and 94. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### ***Claim Rejections - 35 USC § 101/112***

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

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"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-5 and 8-11 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the asserted utility for the inventive sequences as a promoter or regulatory element, while specific, is not a substantial utility for elected SEQ ID NO: 1. Further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use for the reasons set forth below. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

The specification discloses on pages 1 and 5 that the present invention is directed to regulatory elements, specifically promoters, but does not explicitly identify SEQ ID NO: 1 as a regulatory element or promoter anywhere. The specification sets forth definitions for regulatory elements and promoters on pages 9-10, but does not teach anywhere whether elected SEQ ID NO: 1 actually meets any of the definitions set forth in the specification. Table 3 discloses that SEQ ID NO: 1 comprises two possible TATA boxes, from residues 74-88 and 1279-1281. As a single promoter usually comprises a single motif (e.g. one TATA box or CCAAT region), the disclosure for two TATA boxes indicates that SEQ ID NO: 1 may comprise, but not actually BE one or more regulatory elements. No utility has been asserted in the specification for a full-length sequence which merely comprises one or more regulatory elements, but is not, per se, a regulatory element or promoter. That is, if SEQ ID NO: 1 is not a promoter or regulatory element per se, but only comprises such, then there does not appear to be any asserted utility for the entirety of SEQ ID NO: 1. Further research is clearly necessary to determine whether SEQ ID NO: 1, per se, is a regulatory element or promoter. Thus, while a utility as a promoter may be a specific one (i.e. it is not a utility that can be applied to all nucleic acids), this utility has not been established as one which applies to elected SEQ ID NO: 1, therefore the instant claims do not have a specific, substantial, and credible utility. SEQ ID NO: 1 appears to be free of the prior art, therefore there is not well-established utility for SEQ ID NO: 1, or for the instant claims.



Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

Claims 1-5 and 8-11 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

### ***Conclusion***

Claims 1-5 and 8-11 are rejected; claims 6-7 and 12-37, and all sequences other than SEQ ID NO: 1 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN  
PATENT EXAMINER

*Marjorie A. Moran*

mam  
April 5, 2003